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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,129	12/26/2001	Rajneesh Taneja	ABB1259P0072US (6762.US.0	3432

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/036,129	Applicant(s) TANEJA ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Declaration, the Change of Address, the request for Extension of Time (3 months), all filed 07/08/02 and the Information Disclosure Statement (IDS) filed 03/12/02.

Claims 1-29 are pending. Claims 1-29 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 15-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 5-6, recites the phrase "*bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal.*" The claim is indefinite since it does not recite that the Group IA metal is chosen from the Periodic Table of Elements. It is suggested that the recitation of the Group IA metal include a limitation reciting that the Group IA metal is chosen from the periodic table of elements. This applies to independent claims 15 and 26, as well as their dependent claims. Appropriate correction is required.

Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph as being indefinite. Claim 1, line 5 recites the limitation "pharmaceutically acceptable carrier *includes* a bicarbonate salt and a carbonate salt." The term "*includes*" is indefinite because it is unclear which additional components aside from the bicarbonate and carbonate salts are included with the pharmaceutical carrier in the formulation. It is suggested that the term "includes" be either positively recited or deleted. This correction also applies to independent claims 13, 15, 26 and all dependent claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 15-21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips (US Pat. No. 5,840,737; collectively, "Phillips").

Phillips discloses a method for treating gastric acid disorders by administering to a patient a single dose of a pharmaceutical composition including an aqueous solution/suspension of proton pump inhibitors – omeprazole, lansoprazole or other substituted benzimidazoles and derivatives thereof in a pharmaceutically acceptable

carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal (see abstract and claims).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-11, 15-21, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Phillips (US Pat. No. 6,489,346 B1).

Phillips discloses a method for treating acid-related gastrointestinal disorders comprising administering to a patient a non-enteric pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent, wherein the pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal (see Abstract, claims and col. 11, line 13 through col. 14, line 25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8, 10-14, 22 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US Pat. No. 5,840,737) alone or in view of Phillips (US Pat. No. 6,489,346 B1).

Phillips, as discussed above, teaches a method for treating gastric acid disorders by administering to a patient a single dose of a pharmaceutical composition including an aqueous solution/suspension of proton pump inhibitors – omeprazole, lansoprazole or other substituted benzimidazoles and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal (see abstract and claims). Phillips also teaches a pharmaceutical composition, which includes omeprazole or other substituted benzimidazoles and

derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal (see abstract and claims).

Phillips teaches a method for treating gastric acid disorders wherein the Group IA metal is sodium and potassium (see claims 1-3).

It is stated that the pharmaceutical composition is prepared by mixing omeprazole or other substituted benzimadoles and derivatives thereof with a solution including a bicarbonate salt of a Group IA metal. Preferably, omeprazole powder or granules are mixed with a sodium bicarbonate solution to achieve a desired final omeprazole concentration (col. 7, line 50 through col. 8, line 5).

Phillip states that the pharmaceutically acceptable carrier includes the bicarbonate salt of the Group IA metal and can be prepared by mixing the bicarbonate salt of the Group IA metal, which is preferably sodium bicarbonate, with water. The concentration of the bicarbonate salt of the Group IA metal in the composition generally ranges from approximately 5.0% to about 60%. In a preferred embodiment, the preferred salt is sodium bicarbonate and is contained in a concentration of about 8.4% (col. 8, lines 6-17).

Suitable derivatives of omeprazole can be substituted for the omeprazole or other suitable substituted benzimidazoles, wherein these derivatives include lansoprazole (col. 8, lines 41-45).

The pharmaceutical composition can be used for the treatment of gastrointestinal conditions, including, active duodenal ulcers, gastric ulcers, gastroesophageal reflux

disease (GERD), severe erosive esophagitis, poorly responsive systematic GERD, and pathological hypersecretory conditions (col. 8, lines 46-61).

The examples on columns 10-19 further demonstrate various embodiments of the invention in greater detail.

Phillips is deficient only in the sense that he does not explicitly teach the instant ratios. However, in the absence of showing the criticality of the instantly claimed ratios and/or amounts, it is deemed obvious to one of ordinary skill in the art that suitable ratios and/or amounts could be determined through routine or manipulative experimentation.

In addition, the instant claims recite a method for treating gastric acid disorders comprising a non-enteric coated proton pump inhibitor. Phillips teaches a method for treating gastric acid disorders whereby the use of enteric coatings can be used if desired. It is obvious to one of ordinary skill in the art to either include or exclude enteric coatings based on the administration form desired. Such skill is also evident from the reference of Phillips '346 (see below).

Phillips '346 teaches a method for treating acid-related gastrointestinal disorders by providing a solid pharmaceutical composition in a dosage form that is not enteric-coated, and that has active ingredients that include non-enteric coated proton pump inhibitors and at least one buffering agent (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Phillips ('346) within the teachings

of Phillips ('737) because Phillips ('346) explicitly teaches a method for treating acid-related gastrointestinal disorders wherein the composition includes a non-enteric dosage form and also includes active ingredients, such as non-enteric coated proton pump inhibitors and Phillips ('737) also teaches a method for treating gastric acid disorders whereby the composition comprises various proton pump inhibiting compounds, wherein enteric coatings may or may not be included in the formulation. The expected result would be a non-enteric coated formulation for the effective treatment and/or prevention of gastric acid related disorders, as similarly desired by the applicant.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
March 17, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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